Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0893124	07/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
First Care Medical Clinic	404 South Sutherland Avenue, Monroe, NC	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of manufacturer package inserts 7/2/19, the procedure manual was not complete and current for the testing performed. Findings: 1. Review of laboratory procedure manual and manufacturer package inserts revealed the procedures for chemistry and urine drug screen testing failed to include the type and identity of the quality control material used. Examples: a. Review of laboratory procedure and package insert for Alkaline Phosphatase (ALPI) revealed the same statement; "At least once each day of use, analyze two levels of a Quality Control (QC) material with known alkaline

	phosphatase activity." b. Review of laboratory procedure and package insert for Aspartate Aminotransferase (AST) revealed the same statement; "At least once each day of use, analyze two levels of a Quality Control (QC) material with known aspartate aminotransferase activity." c. Review of laboratory procedure for Methadone (METH) revealed, "At least once each day of use, analyze a positive and a negative control relative to the cutoff concentration using a suitable urine based control material." 2. Review of laboratory procedure manual revealed the procedures for urine drug testing failed to include the reference values or cut-off values used to determine positive or negative results for all analytes tested. Example: a. Review of laboratory procedure for urine Cocaine (COC); "Urine Cocaine Metabolite Screen Flex reagent cartridge" revealed, "Results...Qualitative Mode: The results from a COC analysis can be reported qualitatively as negative or positive relative to the 150 or 300 ng/ml cutoff for COC." 3. Review of laboratory procedure for Enzymatic Carbonate (ECO2) revealed the procedure manual did not include a procedure for the current ECO2 testing using the Dimension Flex reagent cartridge. 4. Review of laboratory procedure manual revealed a procedure for Total Enzymatic Carbonate (TCO2), using an electrode method. The laboratory no longer tests for TCO2 using this method. 5. Review of laboratory procedure manual revealed the procedures for chemistry testing failed to include the frequency of calibration for all analytes tested. Example: a. Review of laboratory procedure for Total Bilirubin (TBIL) revealed. "Perform and evaluate a three level calibration as per current calibration guidelines using Dimension TBIL/DBIL Calibrator (Cat. No. DC17) and including quality control materials." .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual 7/2/19, all procedures were not approved, signed, and dated by the current laboratory director before use. Review of the laboratory's procedure manual revealed the current laboratory director failed to sign and date all procedures to indicate review and approval. The following procedures were signed and dated by the previous laboratory director, but had not been approved by the current laboratory director: 1. Quality Assurance Program 2. Troubleshooting Quality Control 3. Proficiency Testing 4. Hematology 5. BD Affirm 6. Dimension chemistry and drug screen 7. Tosoh
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with TP (testing personnel) 7/2/19, the laboratory failed to document dates of discontinuance for procedures no longer in use. Review of the laboratory's procedure manual revealed it included the following procedures no longer used by the laboratory: 1. Procedures for allergy testing on the Immulite 2000 instrument 2. Iron 3. Ferritin 4. Iron Binding

	Capacity During interview at approximately 2:15 p.m., TP #2 stated that he was unsure when the tests were discontinued, but it had been a while.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview on 7/2/19, the laboratory failed to discard supplies that had exceeded the expiration date. During a tour of the laboratory at 12: 15 p.m., the surveyor observed a bottle of expired AHDL Calibrator (Lot Number 8LD077, Expiration Date: 2019-05-01) on the second shelf of laboratory refrigerator #1, available for use. During interview at approximately 12:15 p.m., testing personnel #1 confirmed the calibrator was expired and took possession of it for proper disposal.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Abbott Cell-Dyn 1800 validation records, review of the Hematology policy/ procedure, review of Abbott Cell-Dyn 1800 System Operator's manual, the absence of documentation and interview with TP(testing personnel) on 7/2/19, the laboratory failed to verify the performance specifications of the new Abbott Cell-Dyn 1800 analyzer before routine patient testing and reporting of patient test results. Findings: 1. Review of the Abbott Cell-Dyn 1800 validation records revealed an incomplete accuracy study. The laboratory's Hematology policy/procedure states under Expected Values: Accuracy and Linearity, "...When the instrument is first put into operation an accuracy study is conducted by testing samples on the Cell-Dyn and by a reference lab. The instrument is not used for patient testing until there is evidence that accuracy requirements have been met." During interview at approximately 10:30 a.m., TP #2 stated comparisons were performed in January 2019 for the new analyzer but the comparisons had not been evaluated. Review of the comparison data confirmed there was no evaluation performed to determine if the test results were within acceptable limits in order to verify accuracy of the analyzer. 2. Review of the Abbott Cell-Dyn 1800 validation records revealed a precision study was performed on the analyzer on January 4, 2019. Review of the precision data revealed the CV% (Coefficient of Variation percent) obtained for WBC (White Blood Cell) and RBC (Red Blood Cell) was outside the within-sample precision for WBC and RBC parameters. As stated in the Cell-Dyn 1800 System Operator's manual, the CV% of less than or equal to 2.5% is acceptable for WBC and less than or equal to 1.7% is

	acceptable for RBC . The CV% obtained during the precision study was 3.7 for WBC and 1.8 for RBC. There was no further evaluation documented for the precision study. 3. Review of the Abbott Cell-Dyn 1800 validation records revealed absence of a linearity study. The laboratory's Hematology policy/procedure states, "....Linearity is tested using a stable sample having no interfering substances. The linearity kit can be purchased from Abbott and is required when an instrument is first put into use..." At approximately 10:30 a.m., TP #2 confirmed linearity was not performed on the analyzer. 4. Review of the Abbott Cell-Dyn 1800 validation records revealed no documentation that the laboratory director reviewed or approved the results of the verification studies before the analyzer was put into use.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of a random patient test report and interview with TP (testing personnel) 7/2/19, the laboratory failed to ensure the laboratory's test report included the reference ranges for testing performed. Findings: Review of random computer generated patient report revealed the test report did not include reference ranges for Candida, Gardnerella, and Trichomonas testing that is performed using the BD (Becton Dickinson) Affirm VPIII Microbial Identification System. During interview at approximately 3:00 p.m., TP #2 confirmed the test report was printed from the EMR (Electronic Medical Record) and did not include the reference ranges for Candida, Gardnerella, and Trichomonas.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records 7/2/19, the laboratory director failed to provide overall management and direction for the laboratory. Findings: 1. The laboratory director failed to ensure performance specifications of the new Abbott Cell-Dyn 1800 analyzer were verified before routine patient testing and reporting of patient test results (see D6013). 2. The laboratory director failed to ensure that all proficiency testing results received were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action (see D6018). 3. The laboratory director failed to ensure the maintenance of an effective quality assessment program to identify and correct problems and prevent their recurrence (see D6021). 4. The laboratory director failed to ensure patient test reports included pertinent information required for interpretation (see D6026). 5. The laboratory director failed to ensure an approved, current procedure manual was available to all testing personnel for all aspects of the testing and reporting process (see D6031). This deficiency was previously cited on the 4/8/15 survey.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the Abbott Cell-Dyn 1800 validation records, review of the Hematology policy/ procedure, review of Abbott Cell-Dyn 1800 System Operator's manual, the absence of documentation, and interview with TP (testing personnel) on 7 /2/19, the laboratory director failed to ensure verification procedures were adequate to verify the performance specifications of the new Abbott Cell-Dyn 1800 analyzer before routine patient testing and reporting of patient test results (see D5421).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of 2017, 2018, and 2019 API (American Proficiency Institute) proficiency testing records and interview with TP (testing personnel) 7/2/19, the laboratory director failed to ensure that all proficiency testing results received were reviewed to evaluate the laboratory's performance and identify any problems requiring corrective action. Findings: Review of 2017, 2018, and 2019 API proficiency testing records revealed the following proficiency testing results were not reviewed by the laboratory director: 1. 2017 3rd Chemistry Core test event; 2. 2017 3rd Hematology test event; 3. 2019 1st Chemistry Miscellaneous test event; 4. 2019 1st Hematology test event. During interview at approximately 11:05 a.m., TP #2 confirmed that the results were not signed and dated by the laboratory director to indicate review.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment plan, review of 2018 quality assessment records, and review of patient test reports 7/2/19, the laboratory director failed to ensure the maintenance of an effective quality assessment program designed to identify and correct problems and prevent their recurrence. Findings: 1. The laboratory's quality assessment plan states on page 1 "... B. RESPONSIBILITIES 1. MEDICAL DIRECTOR The Medical Director ... has oversight responsibilities for all activities of the laboratory including but not limited to: a. Assure annual review of Department QA Plans. b. Review remedial action taken as a result of QA activities ... g. Establishing and maintaining QA and Qc programs to assure quality lab services. h. Review corrective action. ..." Review of 2018 quality assessment records revealed "Laboratory Compliance Audits" performed 4/7/18, 7/13/18, and 11/9/18 by the laboratory's former technical consultant had not been signed and dated by the laboratory director to indicate review. 2. The quality assessment program failed to identify problems with test reports identified during the survey (see D5807, D6026). The laboratory's quality assessment plan included a "Patient Requisition and Specimen Labeling" monitor to be performed "On a quarterly basis". On the "Laboratory Compliance Audits" performed 7/13/18 and 11/9/18, the former technical consultant noted "Did not review" for the "Test Tracking System" portion of the audit. There was no documentation available to indicate the monitor was performed during 2018 or 2019. 3. There were no records of quality assessment activity available for 2019.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of random patient test reports (#226663, #201239, #278433, #218660), and interview with staff on 7/2/19, the laboratory director failed to ensure patient test reports included pertinent information required for interpretation of the laboratory's PSA (Prostatic Specific Antigen) and urine drug screen test results. Findings: 1. The laboratory performs PSA testing on the Tosoh AIA-2000 analyzer using the two-site immunoenzymometric assay. The manufacturer's product insert (1002871001-106G, Rev. 10/16) for this test method states, "CAUTION: ...BECAUSE OF DIFFERENCES IN REAGENT SPECIFICITY AND ASSAY METHODS, THE CONCENTRATION OF PSA IN A GIVEN SPECIMEN MAY VARY WITH DEVICES FROM DIFFERENT MANUFACTURERS. VALUES OBTAINED WITH DIFFERENT ASSAY METHODS CANNOT BE USED INTERCHANGEABLY. IT IS MANDATORY THAT RESULTS REPORTED BY THE LABORATORY TO THE PHYSICIAN INCLUDE THE IDENTITY OF THE ASSAY USED...". Review of a random patient test report (#226663) printed from the EMR (Electronic Medical Record) revealed it did not include the method used for PSA. The test method used was included on the

	same patient's test report (#226663) printed from the LIS (Laboratory Information System). During interview at approximately 2:30 p.m., TP #2 confirmed that the PSA test method was not included in the patient's EMR test report. 2. Review of manufacturer's instructions for Amphetamine, Barbiturate, Benzodiazephine, Cocaine, Marijuana, Opiates, Ecstasy and Methadone urine drug screen testing revealed the statement, "The...method provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.". Review of random patient test reports (#201239, #278433, #218660) printed from the EMR revealed the test reports failed to indicate that the urine drug screen results were only preliminary and a more specific method must be used in order to obtain a confirmed analytical result.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, the laboratory director failed to ensure an approved, current procedure manual was available to all testing personnel for all aspects of the testing and reporting process (see D5403, D5407, D5409).